

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 17 JAN 2005

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Applicant's or agent's file reference 67762-010150	FOR FURTHER ACTION		See Form PCT/IPEA/416																
International application No. PCT/US04/08739	International filing date (day/month/year) 22 March 2004 (22.03.2004)	Priority date (day/month/year) 21 March 2003 (21.03.2003)																	
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 35/78 and US Cl.: 424/777																			
Applicant K2A INCORPORATED																			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of ___ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> <p>4. This report contains indications relating to the following items:</p> <table border="0"> <tr> <td><input checked="" type="checkbox"/> Box No. I</td> <td>Basis of the report</td> </tr> <tr> <td><input type="checkbox"/> Box No. II</td> <td>Priority</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td><input type="checkbox"/> Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td><input checked="" type="checkbox"/> Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td><input type="checkbox"/> Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td><input type="checkbox"/> Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td><input type="checkbox"/> Box No. VIII</td> <td>Certain observations on the international application</td> </tr> </table>				<input checked="" type="checkbox"/> Box No. I	Basis of the report	<input type="checkbox"/> Box No. II	Priority	<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/> Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input type="checkbox"/> Box No. VI	Certain documents cited	<input type="checkbox"/> Box No. VII	Certain defects in the international application	<input type="checkbox"/> Box No. VIII	Certain observations on the international application
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Date of submission of the demand 11 October 2004 (11.10.2004)		Date of completion of this report 05 January 2005 (05.01.2005)																	
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230		Authorized officer <i>Dorothea Lawrence</i> Christopher R. Tate Telephone No. 571.272.1600																	

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/08739

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☒ the description:
 - pages 1-78 as originally filed/furnished
 - pages* NONE received by this Authority on _____
 - pages* NONE received by this Authority on _____
- ☒ the claims:
 - pages 79-83 as originally filed/furnished
 - pages* NONE as amended (together with any statement) under Article 19
 - pages* NONE received by this Authority on _____
 - pages* NONE received by this Authority on _____
- ☒ the drawings:
 - pages 1-8 as originally filed/furnished
 - pages* NONE received by this Authority on _____
 - pages* NONE received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☒ The amendments have resulted in the cancellation of:

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/figs NONE
- ☐ the sequence listing (*specify*): NONE
- ☐ any table(s) related to the sequence listing (*specify*): NONE

4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages NONE
- ☐ the claims, Nos. NONE
- ☐ the drawings, sheets/figs NONE
- ☐ the sequence listing (*specify*): NONE
- ☐ any table(s) related to the sequence listing (*specify*): NONE

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/08739

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 10-20 and 30-40

because:

☐ the said international application, or the said claim Nos. _____ relate to the following subject matter which does not require an international preliminary examination (*specify*):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 10-20 and 30-40 are so unclear that no meaningful opinion could be formed (*specify*):

Claims 10-20 and 30-40 are improper multiple dependent claims under PCT Rule 6.4(a).

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/08739**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims <u>1-9 and 21-29</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>4-9 and 24-29</u>	YES
	Claims <u>1-3 and 21-23</u>	NO
Industrial Applicability (IA)	Claims <u>1-9 and 21-29</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and Explanations (Rule 70.7)

Claims 1-3 and 21-23 lack an inventive step under PCT Article 33(3) as being obvious over BOBBIO et al. (Acta Alimentaria, 2002) in view of KITAGAWA et al. (J. Food Science, 1994).

BOBBIO et al. teach preparing a stable, freeze-dried extract of acai (*Euterpe oleracea*) fruit containing high levels of beneficial healthful anthocyanidins therein (see entire document). BOBBIO et al. does not expressly teach various claimed properties of such a freeze-dried product, nor using a different species of *Euterpe*, such as *Euterpe edulus*.

KITAGAWA et al. advantageously disclose that there is a potential market for dried puree of hearts of palm (also known as *Euterpe edulus* fruit) which could be added to instant soup mixtures (see, for example, page 844, second paragraph in second column).

It would have been obvious to one of ordinary skill in the art to prepare a stable freeze-dried product containing high amounts of healthful anthocyanidins from the fruit of *Euterpe oleracea* based upon the beneficial teachings provided by Bobbio. It would also have been obvious, based upon the beneficial teachings provided by Bobbio, to prepare such a stable, freeze-dried product from the fruit (hearts of palm) of *Euterpe edulus* for addition to instant soup mixtures (as advantageously disclosed by Kitagawa) so as to provide a stable, freeze-dried *Euterpe* fruit product which advantageously contains high levels of healthful anthocyanidins. Such freeze-dried fruit products would intrinsically contain fruit pulp therein. The adjustment in conventional working parameters (for example, determining an effective concentration of anthocyanidins therein, and/or other conventional claimed properties of such determining an appropriate water content thereof) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Claims 1-9 and 21-29 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Claims 4-9 and 24-29 meet the criteria set out in PCT Article 33(2) and (3), because the prior art does not teach or fairly suggest the claimed invention.